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IN THE

Supreme Court of the United States

OCTOBER TERM, 1991

GENETICS INSTITUTE, INC.,
AND CHUGAI PHARMACEUTICAL CO., INC.,
Petitioners,

v.

AMGEN, INC.,
Respondent.

PETITION FOR WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF *AMICI CURIAE* OF THE AMERICAN FOUNDATION FOR AIDS RESEARCH, THE AIDS ACTION COMMITTEE OF MASSACHUSETTS, THE AIDS ACTION COUNCIL, AND THE WHITMAN-WALKER CLINIC IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICI CURIAE*

The American Foundation for AIDS Research (AmFAR) is a private, not-for-profit organization dedicated to mobilizing the good will, energy and generosity of Americans and people throughout the world to end the AIDS/HIV epidemic. AmFAR is the leading national non-profit organization devoted to AIDS

research. AmFAR serves as a catalyst by providing start-up funds for innovative projects to fight AIDS/HIV. Since 1985, AmFAR has provided more than $34 million to 550 AIDS research, education and public policy projects.

The AIDS Action Committee of Massachusetts is a non-profit organization dedicated to providing support services for all those diagnosed with Acquired Immune Deficiency Syndrome (AIDS) and HIV disease, while working to prevent the spread of AIDS and to conquer the disease in the future. In furtherance of these ends, the AIDS Action Committee has provided financial support and technical assistance to projects that manage clinical trials of new AIDS treatments and that promote the rapid study and approval of new AIDS therapies.

Similarly, the Whitman-Walker Clinic is the primary provider of community-based AIDS services in the Washington, D.C. metropolitan area. As part of its service to AIDS patients, the Clinic sponsors and participates in various research protocols and clinical trials.

The AIDS Action Council is a non-profit national organization representing both community-based AIDS organizations throughout the nation and individuals affected by and concerned with AIDS and HIV infection. Among its member organizations are groups that conduct AIDS-related clinical research or that provide funding for research aimed at finding treatments and a cure for infection with the HIV virus.

Amici's interests are implicated by this case in two ways. *First*, EPO, the human hormone at issue in this patent dispute, is of vital importance to AIDS patients because EPO is highly successful in treating the hypoplastic anemia that frequently accompanies AIDS. Moreover, EPO is extremely useful in counteracting the anemia that is the major toxic side-effect of treatment with AZT, which is still the most important anti-AIDS medication. EPO thus sigificantly enhances the quality

of life of AIDS patients. *Amici* support a patent law regime that promotes competition in the EPO market by ensuring the maintenance of incentives for competitors to design around the patents relating to the production of EPO by recombinant DNA technology.

Second, genetic engineering technology, which is at issue in this case, holds perhaps the greatest promise for generating effective treatments and even a vaccine for AIDS. A genetically engineered vaccine based on a particular protein found on the outer coat of the AIDS virus has already demonstrated some ability to enhance short-term immune responses in the range that would be expected of an effective vaccine. *See Positive Response: Encouraging Results in the Search for an AIDS Vaccine,* SCIENTIFIC AMERICAN, Aug. 1991, at 26; THE NEW YORK TIMES, June 22, 1991, at 7. Such an experimental vaccine may even have therapeutic uses in treating those already infected with the AIDS virus. *See* SCIENTIFIC AMERICAN, *supra,* at 26. But we remain, at the very least, years away from either a cure or a safe and effective vaccine, and the sharing of research resources among the many scientists and biotechnology companies working on AIDS is vital to those goals, just as such access is vital to biomedical research targeted at other diseases and disorders.[1] It is in the synergy of the efforts of all these parties that hope for progress lies, and *amici*

[1] During the last year, genetic engineering technology has also shown promise in producing a possible vaccine against deadly melanoma and other forms of treatment for other cancers. *See Rosenberg Close to Cancer Vaccine Antigen,* BIOTECHNOLOGY NEWSWATCH, June 17, 1991, at 1. Recombinant DNA is also being used: to isolate and produce other human proteins and macromolecular compounds with therapeutic implications for autoimmune disorders such as rheumatoid arthritis, psoriasis, and atherosclerosis; to develop gene therapies for those afflicted with muscular dystrophy and cystic fibrosis; to pursue better understanding of and treatments for Alzheimer's disease; and even to clone enzymes and proteins capable of regenerating (or preventing damage to) nerve tissue, which holds out hope for those who have suffered a wide variety of brain traumas and nerve damage. *See Research Enlarges Possibilities for Future Recombinant Products,* GENETIC TECHNOLOGY NEWS, Jan. 1991, at 8.

therefore support a patent law regime that requires deposits of patentees' unique biological materials and that thereby ensures access to these vital research resources. In the next four years, 200,000 Americans will die of AIDS; it is already the leading cause of death for people between the ages of 25 and 44. We cannot afford to allow research and innovation in the field of genetic engineering to be hindered by a patent law regime that permits patentees to keep their best mode cell lines, on which further advances could be based, as trade secrets. Time is too short.

SUMMARY OF ARGUMENT

The Federal Circuit has threatened progress and competition in the field of biotechnology with its ruling that a genetic engineer may keep a patent monopoly even while refusing to make deposits of his unique cell lines or other newly created biological materials, thereby withholding those vital research resources from the public and the scientific community. By mandating full disclosure of an invention and the best mode of practicing it, American patent law ensures that progress in the field need not await the end of the patent term, but will instead be promoted as others build on, refine, and design around the invention even while the patentee enjoys the fruits of his monopoly. Such progress is promoted in microbiology, and in genetic engineering in particular, by the Patent Office rule — promulgated under the congressional grant of authority in 35 U.S.C. § 114 — requiring patent applicants to deposit any microorganisms on which their inventions depend that are not "known and readily available to the public." *Manual of Patent Examining Procedure* § 608.01(p)(C) (Rev. 13, Nov. 1989). By promulgating a new rule under which genetic engineers can receive a patent while refusing to make such deposits

and instead keeping their unique new cell lines as trade secrets, the Federal Circuit's decision threatens a central mechanism for the advancement of biomedical research and the medical treatments which flow from it.

ARGUMENT

I. THE OPPORTUNITY OF SCIENTISTS TO EXPERIMENT WITH AND IMPROVE UPON A PATENTEE'S INVENTION DURING THE MONOPOLY PERIOD IS ESSENTIAL TO THE "PROGRESS OF SCIENCE AND USEFUL ARTS."

"From their inception, the federal patent laws have embodied . . . the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy." *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 109 S.Ct. 971, 975 (1989). Full disclosure of the inventor's best mode must be made at the time of the patent application because "[e]arly disclosure . . . provides a basis for further advances in the technology involved." *Report of the President's Comm'n on the Patent System* (1966), *quoted in* Hantman, *Experimental Use as an Exception to Patent Infringement*, 67 J. PAT. & TRADEMARK OFF. SOC'y 617, 642 (1985). Thus the "disclosure requirements of patent law fortify scientific norms promoting publication of research results in replicable form." Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 230 (1987).

An incentive for other scientists and inventors to refine and develop a patentee's invention not only after the patent has expired, but also *during* the 17-year patent monopoly period, is built into 35 U.S.C. § 101, which defines patentable subject matter to include not only "any new and useful process,

machine, manufacture, or composition of matter," but also "any new and useful improvement thereof." The statute "encourages experimental use in order to further increase the fund of human knowledge." Hantman, *supra* at 642.

In accord with this central mission of promoting improvements on patented inventions, the courts for nearly two centuries have recognized an exception to the ban on patent infringement that permits experimental use of another's patented invention.[2] Indeed, it is widely recognized that "[p]erhaps the most important function of early disclosure is to facilitate improvement of the patented invention or invention around the patent" during the patent term. Eisenberg, *supra*, at 219.[3]

This purpose would be frustrated by any rule that inhibited or retarded experimental and research use of the invention disclosed in a patent during the patent term. If the patent laws were interpreted to permit patentees effectively to exclude the scientific community from making full research use of their discoveries, "it could undermine a critical mechanism of the scientific community for facilitating the progress of science." Eisenberg, *supra*, at 225. Surely it "could not have been the intent of Congress that once an invention is patented, and the public has received the 'early disclosure' of the invention, all progress that requires investigation of the discovery claimed in the patent should cease for 17 years." Iraelson, *supra* note 3, at 474.

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[2] *See, e.g., Whittemore* v. *Cutter*, 29 Fed.Cas. 1120, 1121 (C.C.D.Mass. 1813) (No. 17,600) (Story, J.); *Chesterfield* v. *United States*, 159 F.Supp., 371, 375-76 (Ct.Cl. 1958); *Eli Lilly & Co.* v. *Medtronic, Inc.*, 872 F.2d 402, 405-06 (Fed.Cir. 1989). *See also* 35 U.S.C. § 271(e)(1) (not infringement to make, use or sell a patented invention manufactured by genetic engineering if sole purpose is to develop and submit information to FDA on a proposed drug).

[3] *See also Yarway Corp.* v. *Eur-Control USA*, 775 F.2d 268, 277 (Fed.Cir. 1985) (major benefit of patent system is the "incentive" it provides to "design around" other patented inventions); Israelson, *Making, Using, and Selling Without Infringing: An Examination of 35 U.S.C. § 271(e) and the Experimental Use Exception to Patent Infringement*, 16 AM.INTELL.PROP.L.A.Q.J. 457, 472-73 n.77 (1989) ("patent law promotes the progress of the useful arts by fostering activity aimed at 'designing around' a blocking patent").

II. IN THE LIFE SCIENCES, AND PARTICULARLY IN GENETIC ENGINEERING, PUBLIC DEPOSITS OF NEW BIOLOGICAL MATERIALS ARE ESSENTIAL TO THE RESEARCH AND DEVELOPMENT THAT THE PATENT SYSTEM WAS ESTABLISHED TO PROMOTE.

Progress in microbiology and genetic engineering depends upon access to the work of previous researchers and to the special biological materials that they have developed, which are *themselves* critical resources. "A written description of a novel microorganism in a patent specification is of little aid to other scientists if that microorganism is not available through a public depository." I.Cooper, BIOTECHNOLOGY AND THE LAW § 1.02 (1991). Written taxonomic descriptions of newly discovered or genetically engineered microorganisms, like written descriptions of the laboratory techniques used to derive them, are inadequate to place those microorganisms in the hands of other scientists who wish to replicate (and thereby confirm) the original inventive results or to improve upon them. Whatever their length or detail, taxonomic descriptions of living microorganisms are inherently subjective and indeterminate. "Even trained investigators are unable to identify species from them." I.Cooper, *supra*, § 5.05[1][d]. And, no matter how painstakingly they are recorded and set forth, the scientific techniques used to isolate or engineer such microorganisms remain uncertain and subject to unavoidable randomness. Unsurprisingly, both the Patent Office and the courts have heretofore recognized these truths and accordingly required patent applicants to place samples of the microorganisms on which their inventions depend in public depositories, rather than merely setting forth a taxonomic description and recounting how it was obtained.[4]

[4] *See In re Lundak*, 773 F.2d 1216, 1220 (Fed.Cir. 1985) ("When an invention relates to a new biological material, the material may not be reproducible even

This patent system deposit requirement mirrors the practices of the scientific research community, in which scientific journals require contributors to make their biological materials freely available (by deposits or by their own distribution) to others for research purposes. *See, e.g.*, 232 SCIENCE xi (1986) ("Information for Contributors"); 183 VIROLOGY vii (July, 1991) ("Notice to Authors"). Likewise, the Federal Government requires that all who receive funding from the National Institutes of Health or other Public Health Service divisions must make deposits in "the American Type Culture Collection or similar repositories" of all "unique or novel biological materials and resources developed with PHS funds," *because "they otherwise are not truly accessible to the scientific community*." DEPT. HEALTH & HUMAN SERVICES (OASH) Publication No. 90-50.000 (Rev. Oct. 1, 1990) at 8-24 (emphasis added). This Executive Branch rule rests on the conclusion that "[r]estricted availability of unique resources upon which further studies are dependent can impede the advancement of research and the delivery of medical care." *Id.*

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when detailed procedures and a complete taxonomic description are included in the specification."); *Application of Argoudelis*, 434 F.2d 1390, 1392 (C.C.P.A. 1970) ("a unique aspect of using microorganisms as starting materials [for an invention] is that a sufficient description of how to obtain the microorganism from nature cannot be given."); *Ex parte Forman*, 230 USPQ 546, 547-48 (PTO Bd. of Pat. App. and Interferences 1986) ("in the absence of a deposit, one of ordinary skill in the relevant art would not be able to obtain the specific [bacterial] mutant apparently essential to appellants' invention. . . . There do not appear to be any apparently precisely reproducible working examples"); *Ex parte Kropp*, 143 USPQ 148, 151, 152 (Pat.Off.Bd. of App. 1959) ("the [patent] specification could not be reproduced, nor could the antibiotic be produced, since the organism used was not available" from a deposit, even though "the new organism is described in sufficient detail that when another culture of the same organism was found it could be identified as being the same organism, and . . . the methods of finding the organism are well known.").

III. THE FEDERAL CIRCUIT'S DECISION CREATES A NEW RULE UNDER WHICH GENETIC ENGINEERS CAN RECEIVE A PATENT WITHOUT HAVING TO MAKE DEPOSITS, AND IT THEREBY THREATENS A CENTRAL MECHANISM FOR THE ADVANCEMENT OF BIOMEDICAL RESEARCH.

One of the major arguments in favor of patentability for genetically engineered microorganisms that was pressed upon this Court a decade ago in *Diamond* v. *Chakrabarty*, 447 U.S. 303 (1980), was that patent protection could be exchanged for having genetic engineers make deposits of their cell cultures:

> The availability of a subculture is especially important for scientific research, because actual strains are needed for experiments. Yet it is unlikely that commercial firms will deposit newly discovered microorganism cultures in a recognized depository if adequate patent protection is unavailable. The absence of patenting, therefore, would preclude acquisition of strains by researchers and would inhibit the exchange of information that is vital to research.
>
> As an example of the operation of the deposit system, cultures of the [bacterial] strains at issue in this case are on deposit with the U.S. Department of Agriculture Northern Regional Laboratories. If the patent application is upheld, any researcher will be entitled to a subculture for use for experimental purposes.

Brief Amicus Curiae of the American Society for Microbiology in *Diamond* v. *Chakrabarty*, No. 79-136 at 10-11. By allowing respondent Amgen to retain its patent on the genetic engineering tools used to produce EPO, despite its failure to deposit any transfected mammalian cells, the Federal Circuit gave the

patentee both the full benefit of a patent monopoly and the benefit of trade secrecy with respect to all of its host cells.[5] In doing so, it denied both the scientific community and the public at large one of the primary benefits of the patent system: free access by other scientists to the inventor's vitally important research resources. That denial of access will inhibit the ability of others to improve upon or to "design around" Amgen's patent, in contravention of the congressional design as implemented by the Patent Office. *See Yarway Corp.* v. *Eur-Control USA*, 775 F.2d 268, 277 (Fed.Cir. 1985).

Before the decision below, all researchers seeking patent protection knew that they had to deposit their new cell lines if those cell lines were not "known and readily available" in the scientific community. *Manual of Patent Examining Procedure*, § 608.01(p)(C) (Rev. 13, Nov. 1989). Now the Federal Circuit has declared that genetic engineers can refuse to deposit their cell lines — even if they are unique and unavailable to others — so long as the process of deriving them is set forth in written instructions. The presence of this fact-intensive loophole gives patent applicants an incentive to withhold deposits in hope of getting *both* a patent monopoly and a valuable trade secret. Even though the Federal Circuit hypothetically remains free to apply this *ad hoc* analysis in the future to void

[5] Although we understand that petitioner Genetics Institute's complaint is that Amgen's patent application is defective because it was not accompanied by an appropriate cell deposit disclosing the "best mode" of the invention, *see* 35 U.S.C. § 112, we note that Amgen not only failed to deposit its "best mode" cell strain, it also failed, as the trial court noted, to deposit *any* mammalian cell transfected with the EPO gene, whether "best mode" or an inferior mode. The deposits Amgen *did* make at the time it filed its patent application were both worthless and bewildering. It deposited ordinary, untransfected yeast cells — which are commonly used in baking bread and can be obtained from any supermarket — and ordinary, untransfected *E. coli* bacteria — which, among other places, can be found in prodigious quantities in any sample of human feces. Deposits of such mundane materials are of no value to scientists wishing to verify, replicate, refine, experiment or improve upon Amgen's research.

a patent for lack of proper cell deposits, both the disincentive to make deposits, and the court's own tilt on the issue, will remain an obstacle to microbiological research. The Federal Circuit's decision does not "promote the Progress of Science," Art. I, § 8, cl.8, but threatens to stymie it.

CONCLUSION

For these reasons, *amici* respectfully urge this Court to grant the writ and review this decision, which will have momentous consequences for the biomedical research that, as explained above, pages 2-4, holds out the best hope for conquering AIDS and other tenacious threats to human health.

Respectfully submitted,

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